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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,515	03/31/2004	Fernand Labrie	P/1259-771	8218

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NEW YORK, NY 100368403

EXAMINER
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BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/815,515	<b>Applicant(s)</b> LABRIE ET AL.	
	<b>Examiner</b> Barbara P. Badio, Ph.D.	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 is/are allowed.
- 6) ☒ Claim(s) 1 and 3-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/2004;07/2004</u> . | 6) <input type="checkbox"/> Other: ____.  |

**First Office Action on the Merits**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 6-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The court has held that adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, "not a mere wish or plan for obtaining the claimed invention." *Eli Lilly*, 119, F.3d 1559, 1568 (Fed. Cir. 1997). The Federal Circuit has also adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications Under the 35 USC 112, 1<sup>st</sup> "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, "including, inter alia, "functional characteristics when coupled with a known or disclosed correlation between function and structure...". *Enzo Biochem, inc. v. Gen-Probe.*, 296 F.3d, 316, 1324-25 (Fed. Cir. 2002).

The present specification lacks sufficient descriptive support for the inhibitors as recited by the instant claims. For example, apart from EM1404, the present specification lacks correlation between structure and the phrase "inhibitor of type 5  $17\beta$ -hydroxysteroid dehydrogenase" (see page 8, lines 21-23 of the present specification). Because the present specification lacks correlation between said functional characteristics and any structure(s), the skilled artisan would be unable to envision the compounds necessary for practice of the claimed invention. Therefore, the instant claims fail to comply with the written description requirement.

3. Claims 6-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific inhibitors set forth on pages 7-11, does not reasonably provide enablement for all inhibitors of the recited enzymes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are

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taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

The instant claims recite the utilization of inhibitors of various enzymes, for example, type 5  $17\beta$ -hydroxysteroid dehydrogenase and  $5\alpha$ -reductase. However, the present specification lacks structural identifying characteristics of each group of inhibitors. There is also no evidence that there is any correlation between said functional characteristics and any structure(s) apart from the specific compounds set forth in the present specification. Thus, in order to practice the claimed invention commensurate in scope with the instant claims, the skilled artisan would have to first determine the ability of every known compound to inhibit the various enzymes recited by the instant claims. Because the present specification lacks guidance as to compounds encompassed by the recited functional characteristics, for example, inhibitor of type 5  $17\beta$ -hydroxysteroid dehydrogenase, the quantity of experimentation necessary to practice the claimed invention commensurate in scope with the instant claims would be undue.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1 and 3-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for the following reasons:

Claim 1 identifies but does not define  $R_{16\alpha}$ ,  $R_{16\beta}$ ,  $R_{17\alpha}$  and  $R_{17\beta}$ . Claim 1 also defines but does not identify  $R_{16a}$ ,  $R_{16b}$ ,  $R_{17a}$  and  $R_{17b}$ . Should  $R_{16a}$ ,  $R_{16b}$ ,  $R_{17a}$  and  $R_{17b}$  read  $R_{16\alpha}$ ,  $R_{16\beta}$ ,  $R_{17\alpha}$  and  $R_{17\beta}$ ? Correction is required.

Claim 1 also recites "a moiety  $-C^oCR$ ". It is unclear what is intended by said moiety especially what is meant by " $C^o$ ". The present specification set forth "a moiety  $-C\equiv CR$ " (see page 3, line 5 of the present specification). Correction is required.

Claims 1 and 3 recite "a group transformed on the skin into hydroxyl". The present specification lacks definition of what is encompassed by said phrase and, thus, the metes and bound of the claimed invention is indefinite.

Claim 4 defines but does not identify  $R_{16\alpha}$ ,  $R_{16\beta}$  and  $R_{17\alpha}$  and, thus, the claim is indefinite

Claims 6-12 recites inhibitors of various enzymes but does not identify/define a structure associated with each and, thus, the claimed invention is indefinite.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Morrow et al. (J. Med. Chem., 1966).

Morrow et al. teaches several 3-fluoroestra-1,3,5(10)-trienes including 3-fluoro-17 $\alpha$ -methylestra-1,3,5(10)-trien-17 $\beta$ -ol and 3-fluoroestra-1,3,5(10)-trien-17-one and the effect of elimination of the 3-hydroxyl group of natural estrogens (see entire article, especially page 250, compounds III and VII). The compounds and compositions taught by the reference are encompassed by the instant claims.


#### ***Telephone Inquiry***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB

March 8, 2007